



#191B 1032
7/26/03

In re Application of:

Docket No. 00766.000044

YOSHIKI SASAI, ET AL.

Application No.: 09/855,587

Examiner: Thaiann Ton

Filed: May 16, 2001

Group Art Unit: 1632

For: NOVEL DIFFERENTIATION
INDUCING PROCESS OF
PROCESS OF EMBRYONIC STEM
CELL TO ECTODERMAL CELL
AND ITS USE

Date: July 16, 2003

THE COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, VA 22313-1450

RECEIVED
JUL 24 2003
TECH CENTER 1600/2900

Sir:

Transmitted herewith is an Amendment in the above-identified application.

☐ No additional fee is required.

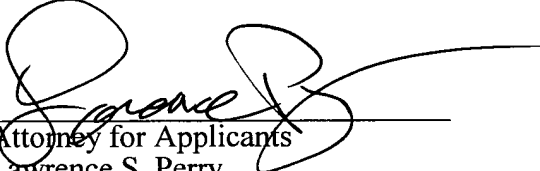
The fee has been calculated as shown below

CLAIMS AS AMENDED						
	(2) CLAIMS REMAINING AFTER AMENDMENT		(4) HIGHEST NO. PREVIOUSLY PAID FOR	(5) PRESENT EXTRA	RATE	ADDITIONAL FEE
TOTAL CLAIMS	* 48	MINUS	** 71	= 0	x \$9 \$18	\$0.00
INDEP. CLAIMS	* 1	MINUS	*** 3	= 0	x \$42 \$84	\$0.00
Fee for Multiple Dependent claims \$140°/\$280						\$280.00
TOTAL ADDITIONAL FEE FOR THIS AMENDMENT---						\$280.00

- * If the entry in Column 2 is less than the entry in Column 4, write "0" in Column 5.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, write "20" in this space.
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, write "3" in this space.

- ☐ Verified Statement claiming small entity status is enclosed, if not filed previously.
- ☒ A check in the amount of \$ 280.00 is enclosed.
- ☐ Charge \$ _____ to Deposit Account No. 06-1205. A duplicate copy of this sheet is enclosed.
- ☒ Any prior general authorization to charge an issue fee under 37 C.F.R. 1.18 to Deposit Account No. 06-1205 is hereby revoked. The Commissioner is hereby authorized to charge any additional fees under 37 C.F.R. 1.16 and 1.17 which may be required during the entire pendency of this application, or to credit any overpayment, to Deposit Account No. 06-1205. A duplicate copy of this paper is enclosed.
- ☒ A check in the amount of \$ 930.00 to cover the fee for a three month extension is enclosed.
- ☒ A check in the amount of \$ 180.00 to cover the Information Disclosure Statement fee is enclosed.
- ☒ Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our address given below.

Respectfully submitted,

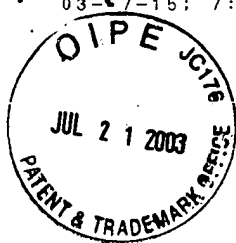


Attorney for Applicants
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LSP\ac

NY_MAIN 363215v1



00766.000044

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
YOSHIKI SASAI, ET AL.) Examiner: Thaiann Ton
Application No.: 09/855,587) Group Art Unit: 1632
Filed: May 16, 2001)
For: NOVEL DIFFERENTIATION)
INDUCING PROCESS OF)
PROCESS OF EMBRYONIC STEM)
CELL TO ECTODERMAL CELL)
AND ITS USE)

Commissioner for Patents
Washington, D.C. 20231

NOTICE RE DEPOSIT OF MICROORGANISMS

Sir:

The above-identified application discloses a cell line which has been deposited with the National Institute of Advance Industrial Science and Technology under the following designation:

Accession Number: FERM BP-7573

The deposit has been made with the National Institute of Advance Industrial Science and Technology under the terms and conditions of the Budapest Treaty. A copy of the International Receipt form is attached. Access to the deposit will be accorded to the Assistant Commissioner upon request and any restrictions upon availability to the public will be irrevocably removed upon granting of any patent issuing on this application or any continuation, divisional or continuation-in-part applications. Maintenance of the deposit is assured for periods of time as specified in the Budapest Treaty.

Kyowa Hakko Kogyo Co., Ltd. will replace the cultures if any should become non-viable for a period of at least five (5) years after the most recent request for

the furnishing of a sample of deposited microorganism, for a period of at least thirty (30) years after the date of deposit or for the enforceable life of such patent, whichever is longer.

The undersigned declares that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

By: Tadashi Hirata
Tadashi Hirata, President
Date: March 24, 2003

NY_MAIN 330791v1

特許手続上の微生物の寄託の国際的承認
に関するブダペスト条約

BUDAPEST TREATY ON THE INTERNATIONAL
RECOGNITION OF THE DEPOSIT OF
MICROORGANISMS FOR THE PURPOSES OF
PATENT PROCEDURE

RECEIPT IN THE CASE OF AN ORIGINAL
DEPOSIT

下記国際寄託当局によって規則7.1に従い
発行される。

issued pursuant to Rule 7.1 by the
INTERNATIONAL DEPOSITARY AUTHORITY
identified at the bottom of this
page.

原寄託についての受託証

氏名(名称)

協和醗酵工業株式会社

取締役社長 平田 正

寄託者

あて名 〒

東京都千代田区大手町一丁目6番1号

殿

1. 微生物の表示	
(寄託者が付した識別のための表示) KM1310	(受託番号) FERM BP- 7573
2. 科学的性質及び分類学上の位置	
1欄の微生物には、次の事項を記載した文書が添付されていた。 ■ 科学的性質 ■ 分類学上の位置	
3. 受領及び受託	
本国際寄託当局は、平成13年 4月27日(原寄託日)に受領した1欄の微生物を受託する。	
4. 移管請求の受領	
本国際寄託当局は、 年 月 日(原寄託日)に1欄の微生物を受領した。 そして、 年 月 日に原寄託よりブダペスト条約に基づく寄託への移管請求を受領した。	
5. 国際寄託当局	
独立行政法人産業技術総合研究所 特許生物寄託センター International Patent Organism Depository 名称: National Institute of Advanced Industrial Science and Technology センター長 小松 泰彦 Dr. Yasuhiko Komatsu, Director あて名: 日本国茨城県つくば市東1丁目1番地1 中央第6 (郵便番号 305-8566) AIST Tsukuba Central 6.1-1, Higashi 1-Chome Tsukuba-shi, Ibaraki-ken 305-8566 Japan 平成13年(2001) 4月27日	

Revised Notice*

AMENDMENTS MAY NOW BE SUBMITTED IN REVISED FORMAT

The United States Patent and Trademark Office (USPTO) is permitting applicants to submit amendments in a revised format as set forth below. Further details of this practice are described in *AMENDMENTS IN A REVISED FORMAT NOW PERMITTED*, signed January 31, 2003, expected to be published in *Official Gazette* on February 25, 2003 (Notice posted on the Office's web site at

<http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/revamdtprac.htm>). The revised amendment format is essentially the same as the amendment format that the Office is considering adopting via a revision to 37 CFR 1.121 (Manner of Making Amendments). The revision to 37 CFR 1.121 (if adopted) will simplify amendment submission and improve file management. The Office plans to adopt such a revision to 37 CFR 1.121 by July of 2003, at which point compliance with revised 37 CFR 1.121 will be mandatory.

Effective immediately, all applicants may submit amendments in reply to Office actions using the following format. Participants in the Office's electronic file wrapper prototype¹ receiving earlier notices of the revised practice may also employ the procedures set out below.

REVISED FORMAT OF AMENDMENTS

Begin on separate sheets:

Each section of an Amendment (e.g., Claim Amendments, Specification Amendments, Drawing Amendments, and Remarks) should begin on a separate sheet. *For example*, in an amendment containing a.) introductory comments, b.) amendments to the claims, c.) amendments to the specification, and d.) remarks, each of these sections must begin on a separate sheet. This will facilitate the process of separately indexing and scanning of each part of an amendment document for placement in an electronic file wrapper.

Two versions of amended part(s) no longer required:

The current requirement in 37 CFR 1.121(b) and (c) to provide two versions (a clean version and a marked up version) of each replacement paragraph, section or claim will be waived where an amendment is submitted in revised format below. The requirements for substitute specifications under 37 CFR 1.125 will be retained.

A) Amendments to the claims:

Each amendment document that includes a change to an existing claim, or submission of a new claim, **must include a complete listing** of all claims in the application. After each claim number, the status must be indicated in a parenthetical expression, and the text of each claim under examination (with markings to show current changes) must be presented. The listing will serve to replace all prior versions of the claims in the application.

- (1) The current status of all of the claims in the application, including any previously canceled or withdrawn claims, must be given. Status is indicated in a parenthetical expression following the claim number by one of the following: (original), (currently amended), (previously amended), (canceled), (withdrawn), (new), (previously added), (reinstated – formerly claim #), (previously reinstated), (re-presented – formerly dependent claim #), or (previously re-presented). The text of all pending claims under examination must be submitted each time any claim is amended. Canceled and withdrawn claims should be indicated by only the claim number and status.
- (2) All claims being currently amended must be presented with markings to indicate the changes that have been made relative to the immediate prior version. The changes in any amended claim should be shown by strikethrough (for deleted matter) or underlining (for added matter). An accompanying clean version is not required and should not be presented. Only claims of the status "currently amended" will include markings.
- (3) The text of pending claims not being amended must be presented in clean version, i.e., without any markings. Any claim text presented in clean version will constitute an assertion that it has not been changed relative to the immediate prior version.

¹ The Office's Electronic File Wrapper prototype program is described in *USPTO ANNOUNCES PROTOTYPE OF IMAGE PROCESSING*, 1265 Off. Gaz. Pat. Office 87 (Dec. 17, 2002) ("Prototype Announcement"), and applies only to Art Units 1634, 2827 and 2834.

- (4) A claim may be canceled by merely providing an instruction to cancel. Listing a claim as canceled will constitute an instruction to cancel. Any claims added by amendment must be indicated as (new) and shall not be underlined.
- (5) All of the claims in each amendment paper must be presented in ascending numerical order. Consecutive canceled or withdrawn claims may be aggregated into one statement (e.g., Claims 1 – 5 (canceled)).

Example of listing of claims (use of the word "claim" before the claim number is optional):

Claims 1-5 (canceled)

Claim 6 (withdrawn)

Claim 7 (previously amended): A bucket with a handle.

Claim 8 (currently amended): A bucket with a ~~green~~ blue handle.

Claim 9 (withdrawn)

Claim 10 (original): The bucket of claim 8 with a wooden handle.

Claim 11 (canceled)

Claim 12 (re-presented – formerly dependent claim 11) A black bucket with a wooden handle.

Claim 13 (previously added): A bucket having a circumferential upper lip.

Claim 14 (new): A bucket with plastic sides and bottom.

B) Amendments to the specification:

Amendments to the specification must be made by presenting a replacement paragraph or section marked up to show changes made relative to the immediate prior version. An accompanying clean version is not required and should not be presented. If a substitute specification is being submitted to incorporate extensive amendments, both a clean version (which will be entered) and a marked up version must be submitted as per current 37 CFR 1.125.

C) Amendments to drawing figures:

Drawing changes must be made by presenting replacement figures which incorporate the desired changes and which comply with § 1.84. An explanation of the changes made must be presented in the remarks section of the amendment. Any replacement drawing sheet must include all of the figures appearing on the immediate prior version of the sheet, even though only one figure may be amended. The figure or figure number of the amended drawing should not be labeled as "amended." If the changes to the drawing figure(s) are not accepted by the examiner, applicant will be notified of any required corrective action in the next Office action. No further drawing submission will be required, unless applicant is notified.

Any questions regarding the submission of amendments pursuant to the revised practice set forth in this flyer should be directed to the following legal advisors in the Office of Patent Legal Administration (OPLA): Elizabeth Dougherty (Elizabeth.Dougherty@uspto.gov), Gena Jones (Eugenia.Jones@uspto.gov) or Joe Narcavage (Joseph.Narcavage@uspto.gov). For information on the waiver or legal aspects of the prototype, please contact Jay Lucas (Jay.Lucas@uspto.gov), Senior Legal Advisor (PGTLA) or Rob Clarke (Robert.Clarke@uspto.gov), Senior Legal Advisor (OPLA). Alternatively, further information may be obtained by calling OPLA at (703) 305-1616.

* Revised Notice: See Sec. B) for changes relating to substitute specifications, and Sec. C) for changes on replacement drawing practice.